



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; comment request:

Clinical Mythteries: A Video Game About Clinical Trials

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* Clinical Mythteries: A Video Game About Clinical Trials.

Type of Information Collection Request: NEW. *Need and Use of Information Collection:* New

England Research Institutes as a contractor for the National Heart Lung and Blood Institute is planning to create an engaging, informational “serious video game” for adolescents about clinical studies which: 1) incorporates core learning objectives; and 2) dispels misconceptions.

Two types of information collection are planned: • usability testing to understand game-play/usability. This information will be collected by focus group and will be digitally recorded 90 minute groups. • A pre/post randomized trial to measure change in knowledge. This information will be collected electronically through on-line questionnaire.

The game will be incorporated with a larger initiative to provide information about clinical research (<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>). *Frequency of*

Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Adolescents – aged 8-14.

The annual reporting burden is as follows: *Estimated Number of Respondents: 6,148; Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: 1.321; and Estimated Total Annual Burden Hours Requested: 370.* The annualized cost to respondents is estimated at: \$3,700. There are no Capital Costs to report. The Operating Costs to collect this information is estimated at \$38642.

(NOTE: The following table should be the same table from section A.12 of the supporting statement)

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Adolescents – Wave one	30	1	1.5	45
Adolescents – Wave two	250	1	1.3	325
Total	370

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Victoria Pemberton, RNC, MS, CCRC, National Heart, Lung and Blood Institute, 6701 Rockledge Drive, Rm. 8109, Bethesda, MD 20892, or call non-toll-free number (301) 435-0510 or E-mail your request, including your address to: pembertonv@mail.nih.gov

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: May 30, 2012

Michael Lauer,
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National Heart, Lung, and Blood Institute, NIH

Dated: June 4, 2012

Lynn Susulske
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